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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,384	11/19/2001	David H. Sherman	600.536US1	8260
21186	7590	06/30/2005	EXAMINER	
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ART UNIT		PAPER NUMBER		
		1656		

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/988,384	SHERMAN ET AL.
Examiner	Art Unit	
Kathleen M. Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 18 April 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 29-55 and 61-63 is/are pending in the application.  
4a) Of the above claim(s) 29,30 and 42-55 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 31-41 and 61-63 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

### *Application Status*

1. A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicant's submission filed on April 18, 2005 has been entered.
  
2. In response to the previous Office action, a Final rejection (mailed on December 16, 2004), Applicants filed a response and amendment received on April 18, 2005. Said amendment amended Claims 31-34, 36, 39, 41, 61, and 62 and added new Claim 63. Thus, Claims 29-55 and 61-63 are pending in the instant Office action.

### *Election*

3. New Claim 63 falls within the elected Group. Claims 29-55 and 61-63 are pending in the instant application. Claims 29, 30, and 42-55 are withdrawn from consideration as non-elected inventions. Claims 31-41 and 61-63 will be examined herein.

### *Priority*

4. As previously noted, the instant application requested the revival of PCT/US99/14398 filed June 25, 1999, which application was abandoned after 20 months of filing (no formal demand for examination was filed by Applicants). Said petition was granted in a paper mailed on April 19, 2004.

The instant application has additionally requested priority via the PCT/US99/14398 to U.S. application 09/105,537 filed on June 26, 1998 wherein the PCT is a continuation-in-part of 09/105,537; said priority is granted herein.

***Withdrawn - Objections to the Specification***

5. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title.
  
6. Previous objection to the specification for the following inconsistencies with respect to the Drawings and their Brief Description in the text is withdrawn by virtue of Applicant's amendment.

***Maintained - Objections to the Specification***

7. Previous objection to the Abstract for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)) is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the Abstract is complete as amended; the Examiner disagrees. "Streptomyces" is not a source species, it is a genus. As previously noted, the source species, *Streptomyces venezuelae*, is crucial in describing the claimed subject matter. Correction is required.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

8. Previous rejection of Claims 31-41 and 61-62 under 35 U.S.C. § 112, first paragraph, written description (pikA promoter), is withdrawn by virtue of Applicant's amendment including structure (90% identical to the EcoRV-EcoRI portion of SEQ ID NO:5) and function (promoter).

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9. Previous rejection of Claims 36, 39-41, and 61 under 35 U.S.C. § 112, first paragraph, written description (TEII domain) is withdrawn by virtue of Applicant's amendment requiring structure and function into said claims.

10. Previous rejection of Claim 61 under 35 U.S.C. § 112, second paragraph, as being indefinite because the claim is wholly unclear is withdrawn by virtue of Applicant's amendment. However, the Examiner disagrees with Applicant's description of the claim in the remarks on page 10 filed April 18, 2005. Claim 61 is drawn to a host cell comprising an expression cassette that contains at least a pikA promoter (or a sequence 90% identical thereto) wherein the host cell contains a met/pik gene cluster on its chromosome that has been altered in is pikA promoter (or a sequence 90% identical thereto).

## NEW ISSUES

### *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 31-41 and 61-63 rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following subject matter are considered new matter:

- a) 90% identical to the EcoRV-EcoRI fragment of SEQ ID NO:5 (Claim 31). While 90% identical fragment of SEQ ID NO:5 are supported (see page 7), 90% identical to this particular fragment is not.
- b) Position 1982 and 3133 of SEQ ID NO:5 (Claims 62-63). While the EcoRV-EcoRI fragment of SEQ ID NO:5 (100% identity) is supported on page 72, lines 31-33, these positions are not. The Examiner finds no evidence that this fragment *has* to be position 1982-3133.
- c) Claim 61 in its entirety. While Example 10 discloses the EcoRV-EcoRI fragment between pikAI and pikRI, which is on SEQ ID NO:5, a host cell comprising an expression cassette that contains at least a pikA promoter (or a sequence 90% identical thereto) wherein the host cell contains a met/pik gene cluster on its chromosome that has been altered in is pikA promoter (or a sequence 90% identical thereto) is not taught.

Applicant is required to delete the alleged new matter or to cite clear support (page and line number) for the alleged new matter.

12. Claims 33-41 and 61 are rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 33, 34, and 36 are drawn to expression cassettes containing sequence that encodes a thioesterase related to SEQ ID NOs:37 or 43. However, SEQ ID NOs: 37 and 43 are disclosed as thioesterase *domains* which are portions of larger proteins, and not independent proteins, as written.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at \*23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which

is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses SEQ ID NOs:37 and 43 as portions of pikAIV and pikAV that are thioesterase *domains*. Moreover, related sequences are described as having 90% identity with said sequences and being a thioesterase domains. The instant claims also include thioesterase independent proteins, which are not described whatsoever in the instant specification. Thus, one of skill in the art would be unable to predict the structure of such independent proteins.

13. Claim 61 is rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 61 is drawn to a host cell with a disrupted chromosome so as to alter polyketide production.

The Court of Appeals for the Federal Circuit has recently held that a “written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as be structure, formula [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials.” University of California v. Eli Lilly and

Co., 1997 U.S. App. LEXIS 18221, at \*23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

While Applicant cite Example 10 as clear support for Claim 61, the Examiner cannot find support for altering the pikAV promoter, even in a specific way. Thus, not a single example of the claimed invention is taught so as to provide a single species of the claimed invention. Neither is a generic description of the structure/function of a mutated promoter taught so as to describe the claimed genus structurally. Thus, one of skill in the art would be unable to predict the structure of claimed host cells.

### ***Summary of Pending Issues***

14. The following is a summary of the issues pending in the instant application:

- a) The Abstract stands objected to for not completely describing the disclosed subject matter.
- b) Claims 31-41 and 61-63 rejected under 35 U.S.C. § 112, first paragraph, new matter.
- c) Claims 33-41 and 61 are rejected under 35 U.S.C. 112, first paragraph, written description.
- d) Claim 61 is rejected under 35 U.S.C. 112, first paragraph, written description.

***Allowable Subject Matter***

15. To assist Applicant in formulating a response, the Examiner notes that the following claim is allowable:

---An isolated DNA molecule comprising a pikA promoter defined by an EcoRV-EcoRI fragment of SEQ ID NO:5.---

***Conclusion***

16. Claims 31-41 and 61-63 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652